Attachment 4

MAY 1 4 2004

510(k) Summary Of Safety and Effectiveness

I. General Information

This Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA of 1990 and 21 CFR § 807.92

Establishment:

- Address: BD Diagnostics, Preanalytical Systems
  1 Becton Drive
  Franklin Lakes, NJ 07417-1885
- Registration Number: 2243072
- Contact Person: Jing Zhang
  Regulatory Affairs Manager
  Telephone no.: 201-847-4717
  Fax No. 201-847-4858
- Date of Summary: 4/23/04

Device:

- Trade Name: BD Vacutainer® Trace Element Serum Plus Tube
  BD Vacutainer® Trace Element K_2EDTA Plus Tube
- Classification Name: Evacuated Blood Collection Tube
- Classification: Class II
- Performance Standards: None Established under 514 of the Food, Drug and Cosmetic Act

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II Effectiveness Information Supporting Substantial Equivalence

- Device Description

  The device description of the BD Vacutainer® Trace Element Serum Plus Tube and the BD Vacutainer® Trace Element K_2EDTA Plus Tube are as follows:
  - Plastic tube (13x100, 6ml)
  - Tube closure: Royal blue Hemogard™ closure
  - Additive: Silica Clot Activator or K_2EDTA

- Intended Use

  The BD Vacutainer® Trace Element Serum Plus Tube and the BD Vacutainer® Trace Element K_2EDTA Plus Tube are plastic evacuated blood collection tubes that provide a means of collecting, transporting, and processing blood in a closed tube. Blood collected in the BD Vacutainer® Trace Element Serum Plus Tube and the BD Vacutainer® Trace Element K_2EDTA Plus Tube is used for trace element testing (e.g., Arsenic, Cadmium, Calcium, Chromium, Copper, Iron, Lead, Magnesium, Manganese, Mercury, Selenium, and Zinc).

- Synopsis of Performance Study Results

  Extensive mechanical and functional testing was performed to demonstrate the devices' safety and effectiveness.

III. Predicate Device Summary Table

Based on comparison of the device features, materials, intended use and performance, the BD Vacutainer® Trace Element Serum Plus Tube and the BD Vacutainer® Trace Element K_2EDTA Plus Tube are shown to be substantially equivalent to the commercially available predicate devices indicated in the table below.

Manufacturer	Predicate Device	510(k) Number
Becton, Dickinson and Company	BD Vacutainer® Trace Element Serum Glass Tube BD Vacutainer® Trace Element Na_2EDTA Glass Tube	Preamendment

Jing Zhang
Regulatory Affairs Manager
BD Diagnostics, Preanalytical Systems
Becton, Dickinson and Company

Date 4/22/04

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 14 2004

Ms. Jing Zhang
Regulatory Affairs Manager
Becton Dickinson & Co.
BD Diagnostics, PreAnalytical System
1 Becton Drive
Franklin Lakes, NJ 07417

Re: k041071
Trade/Device Name: The BD Vacutainer®Trace Element Serum Plus Tube and BD Vacutainer® Trace Element K_2EDTA Plus Tube
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA
Dated: April 23, 2004
Received: April 26, 2004

Dear Ms. Zhang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040171

DEVICE NAME: The BD Vacutainer® Trace Element Serum Plus Tube and BD Vacutainer® Trace Element K_2EDTA Plus Tube

INDICATIONS FOR USE:

The BD Vacutainer® Trace Element Serum Plus Tube and BD Vacutainer® Trace Element K_2EDTA Plus Tube are plastic evacuated blood collection tubes that provide a means of collecting, transporting, and processing blood in a closed tube. Blood collected in the BD Vacutainer® Trace Element Serum Plus Tube and BD Vacutainer® Trace Element K_2EDTA Plus Tube is used for trace element testing (e.g., Arsenic, Cadmium, Calcium, Chromium, Copper, Iron, Lead, Magnesium, Manganese, Mercury, Selenium, and Zinc.).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040171